

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0933273	<b>(X3) Date Survey Completed</b> 07/24/2018
<b>Name of Provider or Supplier</b> Medical Associates Of Brownsville Pa	<b>Street Address, City, State</b> 425 E Los Ebanos Blvd Ste 100, Brownsville, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The laboratory was surveyed on July 24, 2018 and found to be in compliance with the CLIA regulations and recertification is recommended.
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed in interview of facility personnel, the laboratory failed to provide documentation of a competency assessment for each of its technical consultants. The findings were: 1. Review of the laboratory's submitted Form CMS-209 revealed the laboratory director identified two technical consultants. 2. Review of personnel records revealed no competency assessment was available for review for technical consultant one (as listed on Form CMS-209). 3. The above findings were confirmed in interview of technical consultant two (as listed on Form CMS-209) on July 24, 2018 at 10:15 hours in the conference room. Key: CMS - Centers for Medicare and Medicaid Services</p>
<b>D5213</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the laboratory's American Proficiency Institute (API) proficiency testing results from 2016, 2017, and 2018, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of evaluating proficiency testing results returned as 'not graded' by the proficiency testing agency. The findings included: 1. A review of the laboratory's API proficiency testing results from 2016 (events 2 and 3), 2017 (events 1, 2, and 3), and 2018 (event 1) revealed the proficiency agency returned the following results as "Not Graded": 2016 Immunology/Immunochemistry (event 2) Analyte: Anti-RNP/Sm Sample ID: ANA-06 Grade: Not Graded-2 2016 Immunology/Immunochemistry (event 2) Analyte: Antinuclear Antibody Sample ID: ANA-08 Grade: Not Graded-2 2016 Immunology/Immunochemistry (event 2) Analyte: Antinuclear Antibody Sample ID: ANA-10 Grade: Not Graded-2 2016 Immunology/Immunochemistry (event 3) Analyte: Anti-RNP/Sm Sample ID: ANA-14 Grade: Not Graded-2 2016 Immunology/Immunochemistry (event 3) Analyte: Antinuclear Antibody Sample ID: ANA-12 Grade: Not Graded-2 2016 Immunology/Immunochemistry (event 3) Analyte: Antinuclear Antibody Sample ID: ANA-13 Grade: Not Graded-2 2. The proficiency testing agency defined code "2" as: No Consensus. 3. An interview with technical consultant two (as listed on Form CMS-209) on July 24, 2018 at 10:29 hours in the conference room confirmed the findings.

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on laboratory policy, review of the laboratory's calibration verification records for analytes tested on the Ace Alera chemistry analyzer for 2017 and 2018, and confirmed in interview of facility personnel, it was revealed the laboratory failed to have documentation of performing the calibration verification every 6 months. The findings were: 1. Review of the laboratory's policy titled, "Instrument Operation and Maintenance" approved by the laboratory director on August 17, 2005 stated, "Calibration of all laboratory instruments will be every six months, every time there is a complete change in lot numbers, or when controls don't give desired results ..." 2. A

review of the laboratory's calibration verification records for analytes performed on the Ace Alera chemistry analyzer in 2016, 2017, and 2018 revealed the laboratory had documentation of performing calibration verification at the following times: June 2016 December 2016 June 2017 December 2017 3. The calibration verification performed in December 2016 and June 2017 were incomplete. The documentation provided had not been evaluated to ensure the continued accuracy of the analytes throughout the instrument's reportable range. 4. An interview with the technical consultant on July 24, 2018 at 13:10 hours in the conference room confirmed the findings. She reviewed and approved the calibration verifications during the onsite recertification survey.

**D5445**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's Individualized Quality Control Plan (IQCP), and confirmed in interview of facility personnel, the laboratory failed to provide documentation that the QA (quality assessment) portion of the IQCP included procedures for ongoing monitoring of the effectiveness of its IQCP. The findings were: 1. Review of the laboratory's IQCP revealed it was approved by the laboratory director on January 4, 2016. 2. Further review of the study revealed, "B. \_\_\_The IQCP continues to be sufficient to mitigate risk in my laboratory." This portion was also signed on January 4, 2016. 3. Review of the quality assessment portion of the IQCP failed to include procedures for ongoing monitoring of the IQCP. 4. The above findings were confirmed in interview of the technical consultant on July 24, 2018 at 11:30 hours in the conference room.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's personnel records, and confirmed in interview of facility personnel, the technical consultant failed to perform a complete competency assessment for testing personnel two (as listed on Form CMS-209). The findings were: 1. Review of the laboratory's personnel files revealed testing personnel two (as listed on Form CMS-209) had assigned testing responsibilities for moderate complexity testing to include cardiac testing (Troponin, Myoglobin, and CKMB), CBC (Complete Blood Count), and chemistry testing on the Ace Alera chemistry

analyzer. 2. An interview with testing personnel two on July 24, 2018 at 09:50 hours in the laboratory confirmed his moderate complexity testing assignments. When asked if he performs patient cardiac testing and testing on the Ace Alera, he stated, "Yes." He went on to confirm he did not test patient samples on the TOSOH analyzer. 3. Review of the competency assessment for testing personnel two (as listed on Form CMS-209) revealed no tests were listed under, "Testing System(s)." 4. In an interview with the technical consultant on July 24, 2018 at 09:55 hours in the conference room, she revealed she only evaluated him for hematology testing. This confirmed the findings. Key: CMS - Centers for Medicare and Medicaid CKMB - creatine kinase muscle brain